

REMARKS

Examiner interview summary

Attorney Katherine Wrobel participated in a telephonic Examiner interview on September 25, 2009 and proposed an amendment to the independent claims that recites the limitation of the connecting members being ***adhesively*** attached to the anchoring members. Applicant respectfully thanks Examiner Lewis for her time and consideration of proposed claim amendment, and for this opportunity to submit an RCE for review.

Rejections Under 112

The Examiner has rejected claims 1 and 20 under 35 USC 112, first paragraph. In response to this rejection, Applicant has amended Independent claims 1 and 20 to recite the adverb “adhesively” as a replacement for the adverb “permanently.” This modifier pertains to the attachment of connecting members to the anchoring members from which they extend prior to application of the two components device. Support for this modification exists at least at paragraph [0032] of the Specification, which paragraph is reproduced below in additional remarks distinguishing the present invention from previously cited prior art combinations. Applicant respectfully submits that this amendment overcomes the present rejection and that all claims depending for these independent claims are also in condition for allowance. Applicant therefore respectfully requests reconsideration and withdrawal of the present rejection.

Rejections Under 35 USC 103(a)

On January 21, 2009, Applicant submitted arguments in response to rejections under 35 USC 103(a). In light of the present amendments to the claims, Applicant is resubmitting arguments with some refinement based on the presently amended claim language.

The Examiner has rejected claim 1 under 35 USC 103(a) as being unpatentable over US Patent Application Publication No. 2004/0193216 to Duetsch (“Duetsch”) in view of US Patent No. 5,176,703 to Peterson (“Peterson”).

Applicant respectfully submits that the proposed combination of references fails to teach or suggest the limitations of independent claim 1, as currently amended. First, Applicant agrees with the following statement spanning pages 3 and 4 of the office action dated January

21, 2009: "Deutsch fails to teach the first and second adhesive backed anchoring members (18a, 18b) are constructed from elastic material and further fails to teach that the one or more first and second connected members are constructed from substantially inelastic material.

Second, Deutsch fails to teach or suggest an *interlaced, two component* device as taught by Applicant's independent claims 1 and 20 as currently amended. Support for this language exists throughout the Specification and Figures, for example at paragraph [0021], reproduced here for convenience:

[0021] The device of the present invention includes a minimum of one connecting member associated with each component of the two-component device. ***For embodiments in which each component includes two or more connecting members, and the connecting members are attached to pulling elements, the issue of interlacing the connecting members of the two components presents itself.*** This issue was discussed in US Patent No. 6,329,564, the disclosure of which is incorporated herein by reference. Briefly, in order to assemble an interlaced device it may be necessary to construct the first component and the second component independently, and subsequently cut one of the two components in order to interleave connecting members. The cut can be rejoined using an adhesive backed film or tape. Alternatively, at least one of the two components can be incompletely produced enabling interlacing, followed by completion of the device (e.g., by the addition of a pulling element). ***[Emphasis added.]***

Applicant's invention comprises a first component comprising an anchoring member and one or more connecting members extending therefrom, and a second component comprising a second anchoring member and one or more connecting members extending therefrom. As indicated throughout the Specification and figures, for example, FIGS. 1 and 2 and Specification paragraph [0032], the connecting members of the present invention are adhesively attached to their associated anchoring members such that Applicant's invention comprises only two components.

[0032] In embodiments in which the first and second components are not monolithic, anchoring members may be produced from stock having a degree of elasticity. Connecting members are produced separately from stock which is substantially inelastic. One or more first connecting members are then attached (e.g., with adhesive) to a first anchoring member to produce a first component. A second component is similarly constructed.

The two components of Applicant's device are interlaced, having connecting members adhesively attached to respective anchoring members prior to application of the device. This configuration by design aids in placing the anchoring members and simultaneously controlling closure along the entire length of the wound. The Specification describes this inherent functionality at least at paragraph [0012], reproduced here in pertinent part for convenience:

[0012]...Following application of the anchoring members, the laceration is closed by either pushing anchoring members toward one another, or by pulling them together by grasping one or more connecting members from each component and pulling the laceration closed. Very fine adjustment can be made in the X and Y dimension ensuring laceration closure with minimal scarring.

Furthermore, because the two components are interlaced, the one or more connecting members extending from each anchoring element are sufficiently spaced apart to enable fine adjustment during wound closure without any concern of interference between the connecting members. In further support of this argument, Applicant has added the sufficiently spaced limitation to Independent claims 1 and 20. Support for this limitation exists at least in paragraphs [0014] and [0015] of the Specification, reproduced here in pertinent part for convenience:

[0014]...It is extremely important that there be enough distance between adjacent connecting members to facilitate fine adjustment of the device as the second anchoring member is being positioned, and after the two anchoring members are positioned, but prior to fixing their relationship by attaching connecting members to anchoring members.

[0015] As was stated in US Patent No. 6,329,564, the disclosure of which is incorporated herein by reference:

There is no absolute minimum which can be stated with respect to spacing between elongated connectors [connecting members]. Preferred ranges are probably best stated as a percentage of device length (i.e., the dimension of the device generally parallel the laceration or incision). For example, a spacing of between about 5% to about 10% of the bandage length is an example of an appropriate range.

Deutsch, in contrast, teaches a multiple component device including two separately applied flanking strips joined by one or more detachable spanning strips:

[0035] In the present invention, flanking strips 18a and 18b may be attached to

the skin adjacent to the opening edges 14. Spanning strips 20 may then be used to connect the flanking strips 18a and 18b across the opening 10 over the exposed tissue 16

The Deutsch invention is at least a three-component device. The three distinct types of components of the Deutsch device include two flanking strips and one or more individual spanning strips each having free ends that optionally attach to flanking strips. The spanning strips are selectively attachable to the flanking strips and are readily detachable through the use of a well-known non-permanent fastening means, Velcro®:

[0037] Referring now to FIG. 3, each of the flanking strips 18a and 18b is preferably a loop portion of a hook and loop fastener system such as is manufactured under the trade name Velcro with the loop portion positioned away from the surface of the skin 12 so that the "smooth" side of the material is placed against the skin 12.

Deutsch requires such a non-permanent fastening means for the purpose of repeated adjustment and tensioning of the device. Application of the spanning strips follows application of both flanking strips. Because the spanning strips are not adhesively attached to a first anchor member and a second anchor member to form a first component and second component, they must be applied individually following application of the flanking strips, and that precludes the fine adjustment enabled during application of Applicant's interlaced two-component device. If a physician were to apply the spanning strips to both flanking strips prior to application of the Deutsch device, the non-interlaced components might be misaligned, requiring potentially traumatic reapplication of the device to the wound or incision area so that the spanning strips would not overlap or interfere with one another. Such an attempt to pre-attach the flanking strips likely would also produce undesirable spacing, prohibiting sufficient spacing to facilitate fine adjustment. Furthermore, the temporary, non-adhesive Velcro® fastening means could fail during tensioning of the device. The present invention, in contrast, incorporates an adhesive for attaching the connecting members to their respective anchoring member. Generally, adhesives are initially tacky and over a period of time set to a permanent, dried state to prevent separation or at least so that high shear forces are required to separate the adhered elements. For example, Merriam Webster Online Dictionary defines *adhesive* as "tending to adhere or cause adherence" and *adhere* as "to hold fast or stick by or as if by

gluing, suction, grasping, or fusing.” The adhesive of the present invention holds the connecting members fast to the anchoring member, essentially fusing them together to form first and second components, whereas Velcro® by design is a non-permanent means of connecting elements intended for only temporary mating. The Velcro® spanning strips of Deutsch therefore lack the security of the adhesively connected members of the present invention.

Additionally, Deutsch teaches flanking strips comprising notches for curved application along each wound edge, which further highlights the lack of adhesively attached connecting members in an interlaced configuration for enabling fine adjustment of wound edges.

[0039] ... This outer edge may include a series of slits or cutouts 28 passing into the outer edge only partway through the flanking strips 18a and 18b. These cutouts 28 allow the flanking strips 18a and 18b to follow the curvature of the incision edges 14...

Deutsch even suggests cutting the flanking strips into small sections prior to application to piece-wise follow the edges of the wound opening, thereby further increasing the number of device components and precluding any simultaneous, fine adjustment of both wound edges.

[0040]...Alternatively, the flanking strips 18a and 18b may be cut into short lengths to piece-wise follow the edges 14 of the opening 10. The flanking strips 18a and 18b may be precut or cut by the physician using scissors or the like from strips...

The embodiments of the Deutsch device therefore fail to provide any teaching or suggestion of Applicant's interlaced two-component device comprising connecting members adhesively attached to associated anchoring members and sufficiently spaced apart to affect fine adjustment and alignment of wound edges during wound closure. The Deutsch device therefore fails to teach interlaced, adhesively attached components that inherently by design allow for simultaneous fine adjustment of both wound edges.

Peterson fails to cure the deficiencies of Deutsch, particularly with regard to the non-analogous spanning strips of the Deutsch device.

First, the filaments of the Peterson device lack any means for attaching directly to the flat components on either side of a wound edge. Claim 1 recites this direct attachment.

Support for this language exists at least at paragraph [0012] of the Specification, reproduced here in pertinent part for convenience:

[0012]...When the first and second component are positioned to the satisfaction of the physician, or other individual applying the device, the relationship of the two components is fixed by attaching the one or more connecting members of the first component to the anchoring member of the second component, and by attaching the one or more second connecting members of the second device to the anchoring member of the first device.

Instead, the filaments are joined to a tape strip that attaches to a flat component and partially to exposed skin beyond the flexible component. Representative of this teaching is the disclosure in column 4, lines 1-4, which is set forth below for the Examiner's convenience.

By way of illustration in Figs. 3 and 4, strip 30 is pulled off until tape strip 16 is exposed whereupon strip 16 is taped onto the exposed surface of tape 14 and partially onto exposed skin beyond the end of strip 14.

The Peterson filaments therefore are non-analogous with Applicant's elongated connectors that attach to the first and second flat flexible components for finely-adjusted wound closure.

Second, notwithstanding the incongruity issue of Peterson's filaments to Applicant's elongated connectors, the Peterson device's filaments fail to teach the limitation of sufficient spacing for facilitating fine adjustment of the wound closure device. Peterson teaches numerous, closely-spaced filaments. For example, in column 3, line 45, Peterson teaches interwoven filaments having a density of approximately 26 filaments per inch. Such a design, at best, highly restricts a user's ability to adjust the initially applied flat flexible components laterally during wound closure. In fact, since the opposing tape strips are impossible to place perfectly with respect to lateral alignment, the Peterson device as described cannot properly align the wound edges. Applicant's use of sufficiently spaced apart connecting member solves this problem associated with the cited prior art.

Applicant respectfully submits that the proposed combination of references fails to teach or suggest Applicant's invention as claimed in independent claims 1 and 20 as currently amended. Independent claims 1 and 20 thus are in condition for allowance. Applicant respectfully requests reconsideration and withdrawal of the present rejection.

The Examiner has rejected dependent claims 4, 6, 10-12, 18-20, 23, 25, 29-31, 33, 37, and 38 under 35 USC 103(a) as being unpatentable over Deutsch in view of Peterson as applied to claim 1 and further in view of US Patent No. 6,329,564 ("Lebner '564"). Because claims 4, 6, 10-12, 18-19, 23, 25, 29-31, 33, 37, and 38 depend from independent claims 1 and 20, Applicant will address this obviousness rejection at the independent claim level.

Applicant respectfully traverses this rejection. One skilled in the art would not look to Lebner '564 to cure the deficiencies of Deutsch and Peterson. Lebner '564 fails to disclose first and second anchoring members produced from an elastic polymeric material and instead teaches away from that key feature of Applicant's device. Lebner '564 discloses an inelastic device and means for effectively rendering any elastic material inelastic. In contrast, Applicant teaches a device having first and second components comprising anchoring members produced from an elastic polymeric material not reinforced with an inelastic structural component. This is a non-trivial structural distinction that provides distinct functionality.

The elastic components of Applicant's device function differently than the substantially inelastic components of Lebner '564 and solve a unique problem left unaddressed by Lebner '564. Whether or not the first and second components of Lebner '564 are made from a single, substantially inelastic polymeric material or an elastic material reinforced with an inelastic structural component that renders the device substantially inelastic, the first and second components remain inelastic and function as inelastic components. Applicant's specification describes the elastic anchoring member components at paragraph [0031], reproduced here in pertinent part:

For example, a degree of elasticity is a desirable feature in an anchoring member when applied, for example, to an area such as a joint. An anchoring member produced from a film having a degree of elasticity is less likely to release prematurely than an anchoring member produced from a substantially inelastic material when applied to such an area.

Lebner '564 neither teaches nor suggests this key feature of Applicant's invention. In fact, Lebner '564 teaches away from anchoring members produced from an elastic polymeric material for successful application to a flexible area, such as a joint. Instead, Lebner '564 explicitly teaches a substantially inelastic device and provides no motivation for creating Applicant's invention. The substantially inelastic device of Lebner '564 would release from a

flexible area, such as a joint, instead of stretching and flexing with the joint so as to remain securely attached. The elastic anchoring members of Applicant's invention thereby create a device having distinct capabilities not taught or motivated by the Lebner '564 reference.

Applicant respectfully submits that the proposed combination of references fails to teach or suggest Applicant's invention and Lebner '564 in fact teaches away from Applicant's invention as claimed in independent claims 1 and 20 as currently amended. Independent claims 1 and 20 thus are in condition for allowance. Because claims 4, 6, 10-12, and 18-19 depend from claim 1 and because claims 23, 25, 29-31, 33, 37, and 38 depend from claim 20, those dependent claims are all also in condition for allowance. Applicant respectfully requests reconsideration and withdrawal of this rejection.

Summary

In light of the above amendment, consideration of the subject patent application is respectfully requested. Any deficiency or overpayment should be charged or credited to Deposit Account No. 504514.

Respectfully submitted,

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